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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,382	02/19/2004	Hosheng Tu	GLAUKO.1C2C2	3584

20995 7590 11/12/2008

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EXAMINER	
WIEST, PHILIP R	

ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
11/12/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/782,382	TU ET AL.	
	Examiner	Art Unit	
	Phil Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/30/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/30/08 has been entered.

Response to Amendment

2. In the reply filed 9/30/08, applicant amended claim 1. Claims 1-3 are currently pending.

Response to Arguments

3. Applicant's arguments filed 9/30/08 have been fully considered but they are not persuasive. Applicant argues that there is no motivation to combine the Lynch and Ritch patents.

Regarding the filing date of Lynch, while the Lynch provisional does not disclose every aspect of the Lynch patent, every aspect relied upon in the rejection is disclosed in the provisional. The provisional clearly discloses a T-shaped shunt for placement in Schlemm's canal. The disclosed size of the cross tube is irrelevant because changes in size are not considered patentable improvements in the art. See MPEP 2144.04.

Additionally, applicant does not specifically claim the size of the implant, so this argument is moot.

Regarding the combination of Lynch and Ritch, applicant argues that it would not be possible to compact the T-shape of the Lynch device to be inserted using Ritch's cannula. This argument is not persuasive because Ritch clearly suggests folding an implant inside an applicator such that it only unfolds upon placement in the outflow passageway. Additionally, mere changes in size do not constitute patentable improvements in the art. It would have been within the scope of one of ordinary skill in the art at the time of the invention to resize the Lynch and Ritch devices to deliver an L or T shaped shunt through the anterior chamber to Schlemm's canal.

4. Finally, regarding the terminal disclaimer, the rejection over Patent No. 6,780,164 in view of Lynch et al. (US 6,827,700), the examiner cited "the '213' application" in error. The double patenting rejection has been corrected.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-3 rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch (US 6,626,858) in view of Ritch (US 5,092,837).

7. Lynch discloses an ocular shunt implant comprising an outflow portion 25 sized and shaped to be received within Schlemm's canal, and an inflow portion 10 in fluid communication with the outflow portion 25, said inflow portion configured to be disposed in the anterior chamber of the eye (Column 1, Lines 20-27). The long axis of the inflow portion of the implant 10 is disposed at an angle (90 degrees or "L-shaped") to the outflow portion 25 (see Figures 1-4). Lynch, however, does not specifically disclose that the implant is inserted into the eye through the anterior chamber using an applicator.

8. Ritch et al. (hereafter Ritch) teaches a method of implanting a glaucoma shunt in the eye between the anterior chamber and an outflow passageway using an applicator that releasably holds the shunt for implantation into the eye tissue. The implant is in a folded configuration when held by the applicator. When the implant is expelled from the applicator and into the desired location, the folded portions of the implant expand into their unfolded shape, thereby providing anchoring means for the implant. Inserting the implant in a folded configuration allows the size of the incision to be reduced and allows the anchor members to expand to a size that is larger than the incision, thereby securing the implant to the eye. The use of a tubular applicator allows for implants to be inserted into the eye with a single instrument, rather than forming several large incisions on the outer surface of the eye. Additionally, by inserting the applicator through the limbus, the amount of tissue that needs to be punctured to apply the implant is drastically reduced (see figure 3). The use of tubular applicators to insert glaucoma shunts across the anterior chamber in this manner is well established in the art of glaucoma treatment.

9. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the glaucoma implant for draining fluid through Schlemm's canal of Lynch with the method of inserting a folded fluid-draining shunt across the anterior chamber, as suggested by Ritch, in order to provide an alternate method of placing the glaucoma shunt in the trabecular meshwork between the anterior chamber and Schlemm's canal. The method of implanting glaucoma shunts through the anterior chamber is well known in the art because it reduces the size of the required incision and reduces the amount of tissue that must be punctured or cut. Additionally, folding the implant inside the applicator so that the expanded distal portions are able to be inserted through the incision is a well known means for implanting shunts having anchor means or non-axial flow paths. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the glaucoma shunt of Lynch to be folded inside an applicator and implanted into Schlemm's canal through the anterior chamber, as suggested by Ritch, in order to provide a well known, alternate method for implantation and reduce the invasiveness of the surgery.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1 and 2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, and 5 of copending Application No. 11/121584 (PGPubs 2005/0192527). Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a combination of an implant and an actuator for introducing the implant into the eye.

12. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 1-3 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of Patent No. 6,780,164 in view of Lynch et al. (US 6,827,700).

14. Claim 5 of the ‘164 patent discloses an instrument for delivering implants into the body, wherein the implants are held within the body of the instrument. While the '164 patent discloses the invention substantially as claimed, it fails to disclose specifically that the implant is substantially L-shaped. Lynch et al. discloses a glaucoma shunt (i.e.

implant) that may be substantially L-shaped (see figures 1-5). At the time of the invention, it would have been an obvious design choice to modify the shape of the implant of the copending claim 5 to be substantially L-shaped as taught by Lynch to provide greater patency of the implant when disposed in the body would be within the level of ordinary skill in the art.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

//Leslie R. Deak//
Primary Examiner, Art Unit 3761
6 November 2008